

FILED IN CLERK'S OFFICE
U.S.D.C. - Atlanta

Original Court

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
Atlanta Division

FEB 23 2017

JAMES N. HATTEN, Clerk
By: *[Signature]* Deputy Clerk

BRENDA E. CROOK-PETITE-EL
289 BROOKVIEW DRIVE
RIVERDALE GEORGIA 30274
PLAINTIFF

v.
BUMBLE BEE FOODS L.L.C
280 10th AVENUE
SAN DIEGO CA. 92186-5362

DEFENDANT

1:17-CV-0677

PARALLEL STATE TORT
NEGLIGENCE PER SE
FEDERAL VIOLATION
21 C.F.R. PARTS 113,108
O.C.G.A 26-2-20

O.C.G.A 51-1-23
GEORGIA FOOD ACT
O.C.G.A 26-2-26

JURY TRIAL DEMANDED

MASTER COMPLAINT

UNDER The AUTHORITY OF FATHER GOD and GUIDANCE OF HOLY SPIRIT
PLAINTIFF ALLEGES:

(1)

Defendant violated **FEDERAL** regulation 21 CFR 113,108 and **Georgia Compilation Rules and Regulations (Ga.Com. R. & Reg.)** Chapter 40-7-1-.23 **adopted as**

GEORGIA FOOD ACT O.C.G.A 26-2-20 that **parallel Federal** regulation a breach

of **statutory duty** to **comply** with Georgia's specific **Title 21 twin** federal

regulations intended to ensure food safe for human consumption was the

proximate cause of the Plaintiff's permanent heart failing **injury** upon ingestion of

CASTLEBERRY'S HOT DOG CHILI SAUCE UPC Code # 3030000101 that Plaintiff

purchased, and then consumed **without knowledge** of **BOTULINUM TOXIN** the most deadly bacteria known to man. Plaintiff pleads O.C.G.A 9-3-33 "**DISCOVERY RULE**" as result of **Freedom of Information released** from **Inspection** files by **Food & Drug Administration** and the **Georgia Department of Agriculture (exhibit A)**.

1 of 25

(2)

JURISDICTION

28 U.S.C. Sections 1331

THIS CLAIM RISING UNDER 28 UNITED STATES CODE SECTION 1331

The district court SHALL have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the UNITED STATES. This court has original jurisdiction over this action pursuant to violation and failure to comply by state adopted federal regulation 21 c.f.r. 113 & 108.

(3)

United States Constitution Article 3 Chapter 2

The ***judicial Power shall*** extend to all Cases, *in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, of which Shall be made, under their Authority,*

(4)

This Court has ***judicial Power*** extended to this matter pursuant to ***Violation and failure*** to comply with ***Georgia Food ACT a twin Federal Regulations*** TITLE 21

codes of federal regulations parts 113 & 108 respectfully. (21 cfr.113, 108).

CT Corporation 1201 Peachtree Street NE Suite 1240 Atlanta 404-965-2842 is the defendant's ***service agent...***

THE AMOUNT in **CONTROVERSY EXCEEDS 75,000.**

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(5)

This Court has **general personal jurisdiction** over *Bumble Bee Foods LLC* because *Bumble Bee Foods* conducted **continuous business** activities in and throughout the State of Georgia by manufacturing its *Castleberry's Hot Dog Chili Sauce* in Georgia and by advertising, marketing, distributing, and selling Hot Dog Chili sauce in all 50 states throughout the country.

(6)

Bumble Bee Foods is **inspected** by the UNITED STATES DEPARTMENT OF AGRICULTURE- **FOOD SAFETY INSPECTION SERVICE**, FOOD DRUG ADMINISTRATION, licensed and regulated under the GEORGIA DEPARTMENT OF AGRICULTURE inspectors on site during all shifts. Firm's License NO. is 195.

(7)

VENUE under 28 U.S.C. 1391(a) 1391(c)

VENUE is properly laid in the district pursuant to 28 U.S.C 1391(a) because *Bumble Bee Foods LLC* **conducts business** in **Georgia** and within this judicial district within the meaning of 28 U.S.C. 1391(a), as defined in 1391(c), and because a sustainable portion of the events giving rise to these claims **occurred** in **Georgia**, including *Bumble Bee's* manufacturing, and packing of the **contaminated** *Hot Dog Chili Sauce* and of the Plaintiff's purchase and consumption of *Castleberry's* **contaminated** Hot Dog Chili sauce, and the resulting **physical** and **economic** losses and illness.

(8)

**BUMBLE BEES' FEDERAL VIOLATION of REGULATION TITLE 21 CFR 113.40(j)
PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN
HERMETICALLY SEALED CONTAINERS**

The criteria in 113. 10, 113. 40, 113.60, 113.81, 113.87, 113. 89, and 113. 100,

SHALL apply in *determining* whether the facilities, *methods*, practices, and controls *used* by the *commercial processor* in the *manufacture, processing*, or

packing of *low*-acid foods in *hermetically* sealed containers are operated or administered in a manner adequate to *protect* the public health.

(9)

BUMBLE BEE VIOLATED GEORGIA STATE ADOPTED REGULATION 21 CFR 113

STATE OF GEORGIA PARALLEL REGULATION TITLE 21 CFR 113. 40(j)

*Official Compilation RULES and REGULATIONS of the STATE OF GEORGIA
CHAPTER 40-7-1-.23— THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN
HERMETICALLY SEALED CONTAINER.*

The criteria set forth in **21 CFR 113** and 21 CFR 108.25 *SHALL* apply in

determining whether *methods*, practices and controls *used* in the *manufacture, processing*,

packing, and holding of *Low*-Acid Canned Foods are in conformance with manufacturing practices which assure these products are safe for human consumption.

(10)

**BUMBLE BEE failed its duty of care to comply with specific RULES AND
REGULATIONS of Title 21 part 113 ADOPTED BY THE "GEORGIA FOOD ACT"
O.C.G.A. 26-2-20**

(11)
PARTIES

PLAINTIFF a 67 year old Georgian who in good faith purchased two cans of Defendants ***Castleberry's original hot dog chili sauce*** unaware of its poisoned ***BOTULINUM*** contents, (the most ***deadly Bacteria*** known to man) which is a ***diagnostic medical challenge*** to doctors, plaintiff consumed one and a half cans of the chili sauce and became ***violently ill*** as a result was ***admitted*** to the ***intensive care*** unit on ***JULY 19, 2007*** in which plaintiff suffered ***congestive heart failure*** diagnosed as ***unspecified*** T-WAVE abnormality.

DEFENDANT a Georgia corporation ***regulated*** and ***licensed*** by the ***Georgia Department of Agriculture*** its facility ***license number is 195***, owns operates and controls the management of ***Castleberry Foods*** that ***failed*** its statutory duty to comply with regulations of the ***United States Department of Health and Human Services*** under the Food and Drug Administration that ***parallel*** federal ***regulations 21 CFR 113. 40(j)*** adopted by the state ***Georgia Food Act 26-2-20***.

(12)

PUNITIVE DAMAGES O.C.G.A.51-12-5.1

PLAINTIFF PRAYS FOR RELIEF FROM DEFENDANTS Indifference to consequences. FOR RELEASING SPOILED FOOD INTO COMMERCE WITHOUT FURTHER TESTING TO INSURE THAT DEFENDANTS HOT DOG CHILI SAUCE WAS SAFE FOR HUMAN CONSUMPTION.

(a) As used in this Code section, the term “punitive damages” is synonymous with the terms “vindictive damages, “exemplary damages, and other descriptions of additional damages awarded because of aggravating circumstances in order to penalize, punish, or deter a defendant.

(b) Punitive damages may be awarded only in such tort actions in which it is proven by clear and convincing evidence that the defendant’s actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences.

(c) Punitive damages shall be awarded not as compensation to a plaintiff but to solely to punish, penalize, or deter a defendant.

(d)(1) An award of punitive damages must be specifically prayed for in a complaint. In any case in which punitive damages are claims, the Trier of fact

Shall first resolve from the evidence produced at trial whether an award of punitive damages shall be made. This finding *shall* be made especially through an appropriate form of verdict, along with the other required findings.

(e)(1) in a tort case in which the cause of action arises from product liability, there shall be no limitation regarding the amount which may be awarded as

punitive damages. Only one award of punitive damages may be recovered in a Court in this state from a defendant for any act or omission if the cause of action

arises from product liability, regardless of the number of causes of action which may arise from such act or omission.

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(13)

FACTS IN SUPPORT OF PRAYER FOR PUNITIVE DAMAGE

PLAINTIFF's discovery from Freedom of Information FDA Inspection Report No. 1010894 Page 25 of 36

OBSERVATION 1 The system, equipment, and procedures used for *thermal processing* of foods in hermetically sealed containers *were not operated* and administered in a manner that *ensures commercial sterility is achieved*.

Specifically, *the firm had cans* of Castleberry's Hot Dog Chili Sauce from their May8, 2007 production *analyzed for microbiological contamination* by a *recognized outside laboratory*. The *sample was received* by the *lab* on *JULY, 19, 2007* (for future reference *JULY, 19, 2007 Plaintiff was admitted to intensive care unit* with systems of heart failure *unaware food eaten was poisoned*)

Four of the *hermetically sealed cans* in the *firms* sample were **POSITIVE** for **CLOSTRIDIUM BOTULINUM TOXIN..**

SHIPPINS records reviewed on this inspection show this *product was released and shipped* in *interstate commerce*.

REFERENCE: 21 CFR 113.40(j) Supporting Evidence and Relevance: Based on the following observations, commercial sterility was *not* achieved for **HOT DOG CHILI SAUCE**.

FDA sample 428113 collected on 7/18/07 from firm's warehouse Augusta ,Ga and **FDA Samples 420353** collected on 7/19/07 from the same warehouse were **POSITIVE** for **C.BOTULINUM** toxin per **ELISA** test and mouse bio-assay

- 1) The challenges performed revealed both retorts could produce a small portion of finished product that would *not* achieve a thermal process *sufficient to destroy CLOSTRIDIUM BOTULINUM* spores.

THIS WAS A RESULT OF POOR MAINTENANCE OF THE RETORTS AND AN OVERALL FAILURE OF MANAGAMENT TO CORRECT ONGOING DEFICIENCES IN THE FACILITY.

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(14)

COUNT ONE

O.C.G.A 51-1-23 SALE OF UNWHOLESOME PROVISIONS

ANY PERSON WHO KNOWINGLY OR **NEGLIGENTLY SELLS UNWHOLESOME**

PROVISIONS OF ANY KIND TO ANOTHER PERSON, THE DEFECT BEING UNKNOWN

TO THE PURCHASER, BY THE USE OF WHICH DAMAGE RESULTS TO THE PURCHASER OR TO HIS FAMILY, **SHALL BE LIABLE** IN DAMAGES FOR SUCH INJURY.

(15)

FACTS

SALES RECIEPT # 156354 UPC# 303000101 SOLD to Crook on 07/14/07

Crook purchased two cans of food unaware of C. **Botulism** poison ingested one and one half of cans **07/17/07** became gravely ill **admitted on 07/19/07 to cardiac floor not knowing** at that time the **Botulinum** poisoned food she consumed **proximately caused the unspecified T-WAVE ABNORMALITY** (a congestive heart failure).

FDA Establishment **Inspection** Report **1010894** states;

ON 7/19/07 a team of **FDA** Investigators were sent to the firm's warehouse,

during this **inspection** the U.S.Food and Drug Administration **collected samples of Castleberry's brand Hot Dog Chili Sauce** and documentary samples with

accompanying affidavits that were also collected to **establish interstate commerce**.

(16)

On page 5 Of 36 of the inspection report establishes **FDA sample 428113, collected on 7/18/07**, consisting of 17 swollen cans and 12 control cans, **found C. Botulinum toxin** in 16 of 17 swollen cans. This sample included the **same** timestamp and lot code from the May 8, 2007 production as the **can** found in the **Indiana home**.

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(17)

COUNT II

O.C.G.A 26-2-26 ADULTERATED HOT DOG CHILI SAUCE

WHEN FOOD DEEMED **ADULTERATED** A food shall be deemed to be adulterated if:

- (1) It bears or contains **any** poisonous or deleterious substance which may render it **injurious** to health:

(18)

FACTS

O.C.G.A 51-1-23 UNWHOLESOME PROVISIONS

CROOK discovered by FREEDOM OF INFORMATION OF "SUMMARY REPORT"

Food and Drug Administration **OFFICE OF REGULATORY AFFAIRS** Summary

Report for Sample Number 428113 (DATE RECEIVED 07/19/2007)

PRODUCT DESCRIPTION: HOT DOG CHILI SAUCE

(19)

COLLECTION REASON: Collected as follow-up to **suspected** C. bot. **illnesses** associated with possible consumption of suspect code of **Castleberry's Hot Dog Chili Sauce**

Lab Conclusion: Out of twenty-nine subsamples **individually analyzed:** 16 of 17 abnormal subsamples screened **POSITIVE** by ELISA for C. **botulinum** **Toxin type A.**

Sample Received by FDA LABS. DATE: 07/19/2007

Lab Conclusion Date 08/18/2007

Lab Conclusion Made by Call, Veronica L

Collecting District: ATL-DO Collection PACs: 03803A

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(20) COUNT III

DEFENDANT KNOWINGLY RELEASED ADULTERATED HOT DOG CHILI SAUCE INTO INTERSTATE COMMERCE O.C.G.A 26-2-27.1(h)

(h) Any person who **knowingly** introduces into commerce finished foods or finished food ingredients as manufactured at a food processing plant knowing that it contains a substance that would cause a manufactured food bearing or containing the same to be adulterate within the meaning of paragraph (1) of Code Section 26-2-26 **SHALL** be guilty of a felony, and upon conviction, **shall** be punished by imprisonment for not less than one or more than 20 years, a fine not to exceed \$20,000.00, or both. The punishment provided for this subsection **shall be supplemental** to any other **applicable provisions** of law.

(21) FACTS

Plaintiff Crook discovered by FOIA FDA Inspection Report# 1010894

Page 4 of 36 STATES; *Castleberry* management determined they had a **post-processing contamination** problem. The **laboratory results** from both labs showed **mesophilic, anaerobic, spore** (continue to page 5 of 36) **forming bacteria in many** of the **swollen cans** *Bumble Bee* repeatedly stated the **cause** of **spoilage** as **unknown**. It was **evident** the firm **accepted** post-processing as the reason for the swollen cans and **did not investigate** the **issue further** into **other possible** sources.

Page 2 of 36 states an **inquiry** was made into the **firm's knowledge** of any problems with these production dates. **Management responded** by stating they **had determined post-processing contamination** during this timeframe **due to can seam problems**.

PAGE 5 Of 36 **Documentary samples**, with accompanying affidavits, were collected to **establish interstate commerce** . Food **was released** into commerce.

(22)

Crook Pleads "Discovery Rule O.C.G.A. 9-3-33

Plaintiff Pleads that emergency physicians on JULY 19, 2007 informed plaintiff that all test taken returned *normal* leaving plaintiff confused by this information because of the excruciating pain and weakness she was experiencing..

Crook later discovered in her medical records via *nurse notes* that the emergency doctors *did not know* of any *blood test* for *Botulinum*. (EXHIBIT K)

(23)

Crook also discovered in *medical records* nurse notes that state doctor *Mellissa Tobin D'Angello of CDC (Center for Disease Control)* declined testing of plaintiff's stool taken on AUGUST 02, 2007 DECLINED 08/0407 (EXHIBIT H)

(24)

Plaintiff's' investigation discovers the FDA ANALYST REPORT #428113 reveals

Sample Analyst received by FDA LABS on JULY 19, 2007 # 428113 released by the Food and Drug Administration, tested *POSITIVE FOR BOTULINUM TOXIN* TYPE A

A digital photo of Castleberry's Hot Dog Chili Sauce label UPC#3030000101 dated July 19, 2007 with analyst sample # 428113 (exhibit D)

Plaintiff's receipt of purchase on July 14, 2007 reveals the *UPC#3030000101* of two cans at the cost of .55 each purchase from Food Depot Store # 32.

Plaintiff *discovered connection* to Defendants *unwholesome Botulinum toxic* hot dog chili sauce that *proximately* caused plaintiff's congestive heart failing injury on *07/19/07* a diagnostic problem of Botulism plaintiff also suffered.

(25)

DISCOVERY RULE Pursuant to O.C.G.A. 9-3-33 Limitations

FACTS

PLAINTIFF PLEADS: Crook's reliance on emergency doctors to sustain the cause of the heart failure (that plaintiff later discovered in medical record as an

UNSPECIFIED T-WAVE abnormality) was left **without diagnosis** of the cause by medical professionals who suspected the cause to be ischemia coronary artery syndrome.

(26)

The test returned **negative** for **ischemia coronary artery syndrome** as the cause of Crook's **unspecified** T-WAVE abnormality congestive heart failure she suffered.

(27)

Crook's **desperate need** for **doctor's care** informed the defendant by letter that she purchased and ingested Castleberry's recalled hot dog chili

sauce. **Bumble Bee** referred Crook's letter to **(GMA) Grocers Manufacture**

Association of which defendant hired to assist manufactures in solving problems, responded asking for **doctor's diagnosis** to assist with medical bill total \$24,000 for two days of intensive medical care and testing **Southern Medical Center**.

(28)

At that time Plaintiff had **not** received a **diagnosis** from emergency doctors,

unaware of the fact that doctors **did not know of a test for Botulism** or that her **stool** had been **disposed** of because **Dr. D'Angelo** of **Center for Disease Control**

declined to test plaintiff's stool, leaving plaintiff devastated with no insurance to hire a cardiology for medical care plaintiff filed pro se for disability in which she won after three years in pain and **emotional** distress guided by **HOLY SPIRIT**.

(29)

CROOKS' PRAYER FOR RELIEF OF DAMAGES

WHEREFORE, plaintiff pray for judgment against defendant
as follows:

For general damages according to proof;

For special damages according to proof;

For punitive damages;

For loss of earning capacity according to proof;

For loss of career opportunities in motion according to proof;

For pain and suffering;

For mental and physical anguish for exposure to **BOTULINUM** the most
dangerous bacteria known to man in which has a diagnostic challenge;

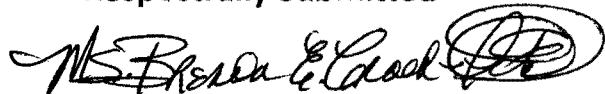
For social and economic loss;

For such other and further relief as this Honorable Court may deem just and
proper.

Dated:

02-23-2017

Respectfully Submitted



MS. Brenda E. Crook-Petite-el

289 Brookview Drive

Riverdale Georgia 30274

770-873-7370 phone

HEBREWS 11:1

EXHIBIT B

UNWHOLESOME PROVISIONS POSTIVE FOR CLOSTRIDUM BOTULINUM FOOD and DRUG Administration Office of Regulatory Affairs

SUMMARY REPORT

FOR SAMPLE NUMBER 428113

RECEIVED BY COLLECTING DISTRICT: ATL-DO

DATE SAMPLE NUMBER 428113

RECEIVED JULY 19, 2007

TESTED

POSITIVE FOR CLOSTRIDUM BOTULINUM

Exhibits

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Food and Drug Administration Office of Regulatory Affairs**Summary Report****For Sample Number: 428113****TD Sample Number:****Import Sample Number:**

This is an accurate reproduction of the original electronic record as of 08/18/2007

Sample Class: Normal Everyday Sample

Sample Origin: Domestic

Sample Basis: Compliance

Sample Flag:

Sample Type: Official

Collecting District: ATL-DO

Home District:

Orig C/R and Records To: ATL-DO

Collection PACs: 03803A

Product Name: Vegetable Protein Products Not Elsewhere Mentioned, N.E.C.; Metal; Commercially Sterile

Product Description: Hot Dog Chili Sauce

Collection Reason: Collected as follow-up to suspected C. bot. illnesses associated with possible consumption of suspect code of Castleberry's Hot Dog Chili Sauce

| | | | |
|-------------|-------------|---------------------------|-----------------------------|
| Lab: ARL | Split Num 0 | Date Received: 07/19/2007 | Date Out of Lab: 08/18/2007 |
| District | | District Conclusion | District |
| Conclusion: | | Made By: | |
| Disposition | | Disposition | Disposition |
| Reason: | | Authorized By: | Authorized Date |

| Performing Org | PAC | LID | PAF | Compliance No | Lab Class-Description | Laboratory Status |
|----------------|--------|-----|-----|---------------|-----------------------|-------------------|
| ARL-MICRO1 | 03803A | | ACD | | 3 - Adverse Findings | Completed |

Lab Conclusion

Out of twenty-nine subsamples individually analyzed: 16 of 17 abnormal subsamples screened positive by ELISA for C. botulinum toxin type A. Abnormal subsamples 1A, 3A, 7A confirmed positive for C. botulinum toxin type A by mouse bio-assay. 12 of 12 normal subsamples screened negative by ELISA for C. botulinum toxin type A. Three subsamples screened negative, 13A, 9, and 3 were confirmed negative by mouse bio-assay.

From abnormal subsamples 1A thru 17A and in normal subsamples 1 thru 11, gram positive rods with terminal spores and free spores observed from cooked meat medium. No organisms observed from normal subsample 12. Lipase activity noted on liver-veal-egg yolk agar for subsamples 1A thru 17A and 1 thru 11. From direct smears, gram positive rods with terminal spores and free spores were observed.

Out of 29 cans analyzed for seam defects:

Thickness measurements are not within specified limits on 23 cans (12 normal, 11 abnormal). Thickness measurements were not taken on 5 swollen cans.

Width measurements are not within specified limits on 3 cans (1 normal, 2 abnormal).

Coverhook measurements are not within specified limits on 6 cans (1 normal, 5 abnormal).

Bodyhook measurements are not within specified limits on 2 cans (1 normal, 1 abnormal).

All other measurements are within specified limits.

Lab Conclusion Date**Lab Conclusion Made By**

08/18/2007

Call, Veronica L

Date: 08/18/2007

Page: 1 of 1

Exhibit

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EXHIBIT A

Crook-Petite-el v. Bumble Bee
Foods LLC

FDA Establishment inspection Report
1010894

Violation of 21 CFR 113.40(j)

Exhibit

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Establishment Inspection Report

Castleberry's Food Company
 Augusta, GA 30901-3929

FEI: 1010894

EI Start: 07/17/2007

EI End: 08/10/2007

Mavity announced that Bumble Bee was voluntarily expanding the recall to include all FDA-regulated and USDA-regulated products manufactured on the (b) (4) line for a period of two years. The significance of the two-year period is all cans receive an ink-jetted lot code that includes a "best by" date. The expiration date this firm has given their products is 24 months. The expanded recall included all products with "best by" dates from July 21, 2007 to July 21, 2009. Please reference the Summary section of this report for the FDA-regulated products under the expanded recall.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**Observations listed on form FDA 483****OBSERVATION 1**

The system, equipment, and procedures used for thermal processing of foods in hermetically sealed containers were not operated and administered in a manner that ensures commercial sterility is achieved.

Specifically, the firm had cans of Castleberry's Hot Dog Chili Sauce from their May 8, 2007 production analyzed for microbiological contamination by a recognized outside laboratory (b) (4). The sample was received by the lab on July 19, 2007 and six cans with a lot code of "Best By May 08 2009 CA CM4 0223" and a timestamp of "0224" were analyzed for Clostridium Botulinum toxin. Four of the hermetically sealed cans in the firm's sample were positive for Clostridium Botulinum toxin. Shipping records reviewed on this inspection show this product was released and shipped in interstate commerce. X 171

Reference: 21 CFR 113.40(j)

Supporting Evidence and Relevance:

Based on the following observations, commercial sterility was not achieved for Hot Dog Chili Sauce:

- 1) FDA sample 428113 collected on 7/18/07 from the firm's warehouse located (b) (4) Augusta, GA 30901 and FDA samples 420352 and 420353 collected on 7/19/07 from the same warehouse were positive for C. Botulinum toxin per ELISA tests and mouse bio-assay.
- 2) The challenges performed on (b) (4) revealed both retorts could produce a small portion of finished product that would not achieve a thermal process sufficient to destroy Clostridium Botulinum spores. This was a result of poor maintenance of the retorts and an overall failure of management to correct ongoing deficiencies in the facility.

EXHIBIT B

UNWHOLESOME PROVISIONS POSTIVE FOR CLOSTRIDUM BOTULINUM FOOD and DRUG Administration Office of Regulatory Affairs

SUMMARY REPORT

FOR SAMPLE NUMBER 428113

RECEIVED BY COLLECTING DISTRICT: ATL-DO

DATE SAMPLE NUMBER 428113

RECEIVED JULY 19, 2007

TESTED

POSITIVE FOR CLOSTRIDUM BOTULINUM

Exhibit

18 of 25

Food and Drug Administration Office of Regulatory Affairs**Summary Report****For Sample Number: 428113****TD Sample Number:****Import Sample Number**

This is an accurate reproduction of the original electronic record as of 08/18/2007

Sample Class: Normal Everyday Sample**Sample Origin:** Domestic**Sample Basis:** Compliance**Sample Flag:****Sample Type:** Official**Collecting District:** ATL-DO**Home District:****Orig C/R and Records To:** ATL-DO**Collection PACs:** 03803A**Product Name:** Vegetable Protein Products Not Elsewhere Mentioned, N.E.C.; Metal; Commercially Sterile**Product Description:** Hot Dog Chili Sauce**Collection Reason:** Collected as follow-up to suspected C. bot. illnesses associated with possible consumption of suspect code of Castleberry's Hot Dog Chili Sauce

| | | | |
|--------------------|--------------------|----------------------------------|------------------------------------|
| Lab: ARL | Split Num 0 | Date Received: 07/19/2007 | Date Out of Lab: 08/18/2007 |
| District | | District Conclusion | District |
| Conclusion: | | Made By: | |
| Disposition | | Disposition | Disposition |
| Reason: | | Authorized By: | Authorized Date |

| | | | | | | |
|-----------------------|------------|------------|------------|----------------------|------------------------------|--------------------------|
| Performing Org | PAC | LID | PAF | Compliance No | Lab Class-Description | Laboratory Status |
| ARL-MICRO1 | 03803A | | ACD | | 3 - Adverse Findings | Completed |

Lab Conclusion

Out of twenty-nine subsamples individually analyzed: 16 of 17 abnormal subsamples screened positive by ELISA for C. botulinum toxin type A. Abnormal subsamples 1A, 3A, 7A confirmed positive for C. botulinum toxin type A by mouse bio-assay. 12 of 12 normal subsamples screened negative by ELISA for C. botulinum toxin type A. Three subsamples screened negative, 13A, 9, and 3 were confirmed negative by mouse bio-assay.

From abnormal subsamples 1A thru 17A and in normal subsamples 1 thru 11, gram positive rods with terminal spores and free spores observed from cooked meat medium. No organisms observed from normal subsample 12. Lipase activity noted on liver-veal-egg yolk agar for subsamples 1A thru 17A and 1 thru 11. From direct smears, gram positive rods with terminal spores and free spores were observed.

Out of 29 cans analyzed for seam defects:

Thickness measurements are not within specified limits on 23 cans (12 normal, 11 abnormal). Thickness measurements were not taken on 5 swollen cans.

Width measurements are not within specified limits on 3 cans (1 normal, 2 abnormal).

Coverhook measurements are not within specified limits on 6 cans (1 normal, 5 abnormal).

Bodyhook measurements are not within specified limits on 2 cans (1 normal, 1 abnormal).

All other measurements are within specified limits.

Lab Conclusion Date**Lab Conclusion Made By**

08/18/2007

Call, Veronica L
VLL

Spilts

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EXHIBIT C

PURCHASE OF UNWHOLESOME

PROVISION UPC 303000101

RECIPT NUMBER 156354

FOOD DEPOT RIVERDALE, GA.

DATE PURCHASED *JULY 14, 2007*

Exhibit

20 of 25

Reg Price = 1.38
 CK LT TUNA WATER 1 0.59 0.59 T
 04800000024
 HOT DOG CHILI 1 0.55 0.55 T
 03030000101
 HOT DOG CHILI 1 0.55 0.55 T
 03030000101
 SR FLOUR 1 0.77 0.77 T
 JUMBO BEEF FRANK 1 1.88 1.88 TPr
 01890002827
 Promo Savings = 0.01
 Reg Price = 1.89
 JUMBO BEEF FRANK 1 1.88 1.88 TPr
 01890002827
 Promo Savings = 0.01
 Reg Price = 1.89
 CLAXTON WINGS BON 1 7.53 7.53 T
 29582500000
 BRIGHT & EARLY 1 0.95 0.95 T
 02500002624
 CHEDDR SHARP SHRE 1 1.69 1.69 T
 05300005361
 GRADE A MEDIUM 1 2.35 2.35 T
 07809100012
 LIQ BLEACH REGULA 1 1.35 1.35 S
 04480002510
 BUDWEISER 12PAK C 1 8.95 8.95 S
 01820011047
 NEWPORT MEN 1 3.47 3.47 S

SIGNATURE
 CHANGE DUE 0.00

YOU SAVED \$ 0.87
 Items = 24

Receipt #: 156354
 Clerk: 205 - MARY
 Register #: 1
 Drawer #: 7
 Date/Time: 07/14/2007 14:36:24

Food Depot #31
 6642 HIGHWAY 85
 RIVERDALE, GA 30274
 (770)996-9626

Purchase \$ 48.96

VISA # XXXXXXXXXXXX6202
 Auth # 014531 Exp Date 08/10
 Lane # 01 Checker # 205
 07/14/07 14:32 Ref/Seq # 411212
 WinFPS Sequence # 411212

04800000024
 HOT DOG CHILI 1 0.55 0.55 T
 03030000101
 HOT DOG CHILI 1 0.55 0.55 T
 03030000101
 SR FLOUR 1 0.77 0.77 T
 JUMBO BEEF FRANK 1 1.88 1.88 TPr
 01890002827
 Promo Savings = 0.01
 Reg Price = 1.89
 JUMBO BEEF FRANK 1 1.88 1.88 TPr
 01890002827
 Promo Savings = 0.01
 Reg Price = 1.89
 CLAXTON WINGS BON 1 7.53 7.53 T
 29582500000
 BRIGHT & EARLY 1 0.95 0.95 T
 02500002624
 CHEDDR SHARP SHRE 1 1.69 1.69 T
 05300005361
 GRADE A MEDIUM 1 2.35 2.35 T
 07809100012
 LIQ BLEACH REGULA 1 1.35 1.35 S
 04480002510
 BUDWEISER 12PAK C 1 8.95 8.95 S
 01820011047
 NEWPORT MEN 1 3.47 3.47 S

SIGNATURE
 CHANGE DUE 0.00

YOU SAVED \$ 0.87
 Items = 24

Receipt #: 156354
 Clerk: 205 - MARY
 Register #: 1
 Drawer #: 7
 Date/Time: 07/14/2007 14:36:24

Food Depot #31
 6642 HIGHWAY 85
 RIVERDALE, GA 30274
 (770)996-9626

Purchase \$ 48.96

VISA # XXXXXXXXXXXX6202
 Auth # 014531 Exp Date 08/10
 Lane # 01 Checker # 205
 07/14/07 14:32 Ref/Seq # 411212
 WinFPS Sequence # 411212

Ed

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EXIHIBIT D PHOTO OF LABEL

***DIGITAL* PHOTOCOPY OF ORIGINAL**

LABELING CASTLEBERRY'S

HOT DOG CHILI SAUCE

UPC#3030000101

SAMPLE NUMBER

***428113* 7/18/07**

SIGNED BY RICK A CROUCH

Exhibit

22 of 25

nutrition Facts

Size 1 Tbsp (16g)
s Per Container About 18

Per Serving
es 10 Calories from Fat 5
% Daily Value*

Fat 0.5g 1%

Fat 0g

in 70mg 3%

Carbohydrate 1g 0%

ry Fiber less than 1g 2%

n 1g

A6%

Trace amounts of substances for
iron, calcium and zinc

*Percent Daily Values are based on a diet of other people's secrets.

Castleberry's

Good Food. Good Value.
Since 1926

429113
718107
P11220

Castleberry's

07100107 RAC

98% Fat Free
For A Low Carb Lifestyle

HOT DOG
CHILI SAUCE

ORIGINAL

NO
Preservatives



Original Photography of Original Labeling

07100107 RAC

23 of 25

signed

EXHIBIT E

ID:001092109

DATE JULY 19, 2007
SOUTHERN REGIONAL MEDICAL
CENTER

ECG ROUTINE RECORD

NONSPECIFIC T WAVE

ABNORMALITY NOW EVIDENT
IN ANTEROLATERAL LEADS..

Exhibit

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ID:001092109

19-JUL-2007 10:45:54

SOUTHERN REGIONAL MEDICAL CENTER-ER

ROUTINE RECORD

KOOKPETITE, BRENDA

FEB-1950 (57 yr)
 male Black
 21b
 om:16
 c:2

| | | |
|--------------|----------|-----|
| Vent. rate | 65 | BPM |
| PR interval | 176 | ms |
| QRS duration | 84 | ms |
| QT/QTc | 392/407 | ms |
| P-R-T axes | 18 -5 -5 | |

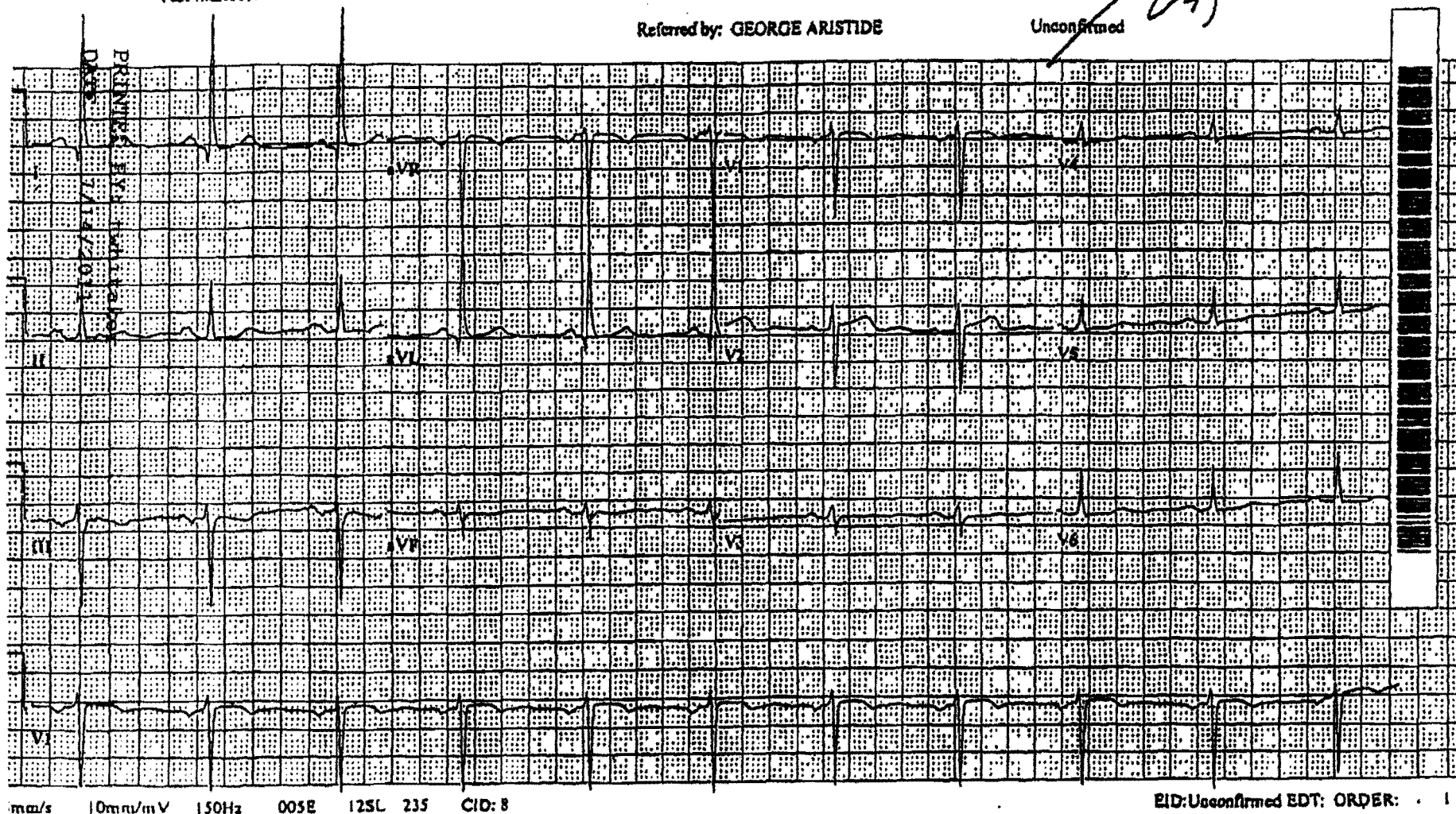
Normal sinus rhythm
 Voltage criteria for left ventricular hypertrophy
 Nonspecific T wave abnormality
 Abnormal ECG

When compared with ECG of 01-DEC-2006 12:22,
 Nonspecific T wave abnormality now evident in
 Anterolateral leads

Technician: LEON HENRY
 Test ind: HTN

Referred by: GEORGE ARISTIDE

Unconfirmed



mm/s 10mm/mV 150Hz 005E 12SL 235 CID: 8

EID: Unconfirmed EDT: ORDER: . 1

Page 1 of 1

720000 224

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skid